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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,818	01/26/2004	Patricia A. Brown	108328.00170 (AVSI-0033)	8276

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JACKSON WALKER LLP
901 MAIN STREET
SUITE 6000
DALLAS, TX 75202-3797

EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,818	BROWN ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-20,22-28,30-77,79,80,86,88,89,97 and 99* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,15-20,22-28,30,34-48,52-62,64-68,70-74 and 76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/18/05;4/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Attachments

Continuation of Disposition of Claims: Claims withdrawn from consideration are 12-14,31-33,49-51,63,69,75,77,79,80,86,88,89,97 and 99.

DETAILED ACTION

Claims 1-9, 1-20, 22-28, 30-77, 79, 80, 86, 88, 89, 97, and 99 are pending in the instant application.

Applicant's election with traverse of Group 1 and SEQ ID NO: 1 in the reply filed on 2/15/06 is acknowledged. The traversal is on the ground(s) that the Examiner has not demonstrated that the various inventions are independent and distinct, and that there is a serious search burden. Applicant argues that the restricted claims are method claims so it is improper to restrict them based on different compositions that are employed in the method. This is not found persuasive because if the compositions are patentably distinct, it follows that methods of using them may also be patentably distinct.. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a). Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. The search and examination of nucleic acid

sequences encoding 48 different peptides is a considerable burden on the Examiner. Furthermore, the elected sequence is structurally and functionally distinct from wild type GHRH in that it is protease resistant and causes higher GH secretion. See US Patent 6,551,996, column 19, lines 24-46, column 21, lines 19-30, and column 22, lines 37-39. For these reasons the requirement is still deemed proper and is therefore made FINAL. Applicant is reminded that groups 1-57 are linked, and that if the linking claims are found to be allowable, then the inventions will be rejoined.

Claims 12-14, 31-33, 49-51, 63, 69, 75, 77, 79, 80, 86, 88, 89, 97, and 99 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. It is not clear that these sequences encode SEQ ID NO:1. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/15/06. Claims 11, 30, 48, 62, 68, and 74 are rejoined because they are drawn to vectors encoding SEQ ID NO:1 (HV-GHRH).

Claims 1-9, 11-20, 22-28, 30-77, 79, 80, 86, 88, 89, 97, and 99 are pending in the instant application.

Claims 1-9, 11, 15-20, 22-28, 30, 34-48, 52-62, 64-68, 70-74, and 76 are under consideration in this Office Action.

Rejections Withdrawn

The rejections under 35 USC 102 and 103 over Schwartz et al (US Patent 6,423,693) are withdrawn in view of Applicant's amendments and election of SEQ ID NO:1.

Specification

The specification should be amended in paragraph 10 at page 6, and at paragraph 167 on page 56, to indicate the issuance of Application No. 09/624,268 as US Patent 6,551,996.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 30, 48, 62, 68, and 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11, 30, 48, 62, 68, and 74 are indefinite because it is not clear if the claim phrase "a HV-GHRH plasmid (SEQ ID NO: 11)" is to be interpreted broadly as any plasmid comprising a sequence encoding HV-GHRH, wherein SEQ ID NO:11 is an example of such a plasmid, or whether the claim is intended to be limited to SEQ ID NO: 11.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 11, 15-20, 22-28, 30, 34-38, 40-47, and 52-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-9, 15-19, 22-28, 34-38, 40-47, 52-56 are drawn to the genus of nucleic acid constructs encoding GHRH or a functional biological equivalent thereof. The specification at page 22, paragraph 69 defines GHRH as any hormone that facilitates or stimulates release of growth hormone, and in a lesser extent, other pituitary hormones such as prolactin. At page 15, paragraph 28, the specification defines "functional biological equivalent" of GHRH as "a polypeptide that has been engineered to contain a distinct amino acid sequence while simultaneously having similar or improved biologically activity when compared to the GHRH polypeptide." So, the encoded polypeptide is limited only by function, and not by structure.

The prior art indicates that there is more than one type of sequence that can stimulate release of growth hormone, e.g. the peptide ghrelin has this property (see Kojima et al (Nature 402:656-660, 1999). However a sequence alignment between porcine ghrelin and SEQ ID NO:1 showed no significant sequence similarity (see attachment), indicating a high degree of variability in the sequences that are capable of causing secretion of growth hormone. Also, MPEP 2163 states:

> A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient

identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

The specification as filed discloses 48 modified forms of GHRH, which vary at positions 1, 2, 15, 27, and 28 (i.e. SEQ ID NO:6), and a wide variety of GHRHs from various species were known in the prior art, including human, bovine, porcine, ovine, rat, mouse, and chicken. This would convey to one of skill in the art that Applicant was in possession of the genus of GHRH proteins, as the term is understood in the art, but not as defined by the specification (i.e. Applicant does not appear to be in possession of the genus of any and all peptides that facilitate or stimulates release of growth hormone). Because the specification explicitly defines GHRH in terms that would include other growth hormone releasing proteins, such as ghrelin, but does not provide a description of the structural characteristics that are required to provide the requisite function, one of skill in the art could not conclude that Applicant was in possession of members of the claimed genus other than SEQ ID NO:6.

Claims 1-9, 11, 15-20, 22-28, 30, 34-48, 52-57 are drawn to the genus of synthetic muscle-specific promoters. The specification discloses two examples of this genus (see e.g. Table 2 at page 40). It is apparent to one of skill in the art that there is a wide variety of proteins that are specific to muscles, e.g. troponins C, I, and T, dystrophin, myosin, beta actin, muscle creatine kinase, etc. However, the specification does not disclose the structures that are required to confer muscle-specific activity of the promoters governing expression of these genes. Therefore, although only two species are disclosed, the specification fails to identify relevant identifying characteristics, such as a correlation between structure and function, that are required

for the claimed function. As a result, one of skill in the art could not conclude that Applicant was in possession of the claimed genus at the time the application was filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 11, 18-20, 22-28, 30, 37-48, 55-62, 65-68, 71-74 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz et al (US Patent 6,551,996) as evidenced by Aihara et al (Nature Biotech. 16: 867-870, 1998). The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Schwartz taught a method of injecting into muscle of a farm animal a plasmid vector encoding SEQ ID NO:1 (HV-GHRH, an optimized protease resistant form of GHRH) under the control of a synthetic muscle specific promoter (SPc5-12). The site of

injection was subsequently subjected to electroporation. See column 6, lines 15-24, column 22, lines 10-30. The method is intended to improve growth performance and increase the efficiency of the animal. See abstract, column 8, lines 24-60, and column 17, lines 31-34. Delivery need not be by electroporation, but may also use viral or liposomal vectors. See column 10, lines 7-12 and column 18, lines 33-39.

In describing the electroporation technique Schwartz refers to the Aihara reference. Aihara taught a method of electroporating nucleic acids into muscle by inserting electrode needles into muscle such that they encompassed the site into which DNA is injected. See page 867, column 2, second full paragraph. So, it is clear that the method of Schwartz includes delivery of nucleic acid to an area of tissue that is penetrated with a plurality of needles.

Although Schwartz is silent with respect to an involuntary cull and body condition score, Schwartz anticipates all of the claimed active method steps, so the functional effects of the claimed methods are considered to be inherent in the method steps taught by Schwartz.

Claims 11, 30, 48, 62, 68, 74 are included in this rejection because they were interpreted as being broadly drawn to any plasmid comprising HV-GHRH. The specification does not define the term "about" as used in the claim term "about 2mg." This term has been interpreted broadly to embrace the teachings of Schwartz, appearing e.g. in claim 8, is interpreted broadly as reading on the 10mg dose disclosed by Schwartz in example 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 15-17, 23, 26, 34-36, 44, 52-54, 58, 64, 66, 70, 72, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al (US Patent 6,551,996) in view of Fewell et al (US 2003/0109478).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Schwartz taught a method of injecting into muscle of a farm animal a plasmid vector encoding SEQ ID NO:1 (HV-GHRH, an optimized protease resistant form of GHRH) under the control of a synthetic muscle specific promoter (SPc5-12). The site of injection was subsequently subjected to electroporation. See column 6, lines 15-24, column 22, lines 10-30. The method is intended to improve growth performance and increase the efficiency of the animal. See abstract, column 8, lines 24-60, and column 17, lines 31-34. Delivery need not be by electroporation, but may also use viral or liposomal vectors. See column 10, lines 7-12 and column 18, lines 33-39.

Schwartz did not teach a transfection facilitating polypeptide.

Fewell taught a method of improving delivery of a nucleic acid expression construct to muscle cells in vivo comprising introducing into the muscle a nucleic acid expression construct and poly-L-glutamate, and electroporating the muscle tissue using needle electrodes. See entire document, e.g. first sentence of paragraph 109 at page 11, paragraphs 113 and 114, paragraph 123 bridging pages 12 and 13, paragraph 128 at page 13, and claim 79.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the poly-L-glutamate of Fewell in the method of Schwartz in order to obtain the reasonably expected improvement in delivery and expression.

Although the cited references are silent with respect to an involuntary cull and body condition score, the combined references render obvious all of the claimed active method steps, so the functional effects of the methods are considered to be inherent.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 18-20, 22-28, 37-47, 55-61, 65-67, 71-73 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-23 of U.S. Patent No. 6,423,693, in view of Schwartz et al (US Patent 6,551,996).

Claims 21-23 of '693 are drawn to methods of delivering to muscle cells in vivo an expression vector encoding GHRH, wherein the vector comprises 5' and 3' UTRs. The portion of the specification supporting the claims indicates that method is intended for livestock improvement. See column 3, lines 8 and 9, and column 35, lines 20-41.

The '693 patent does not claim a synthetic muscle specific promoter.

The '996 patent taught a method of injecting into muscle of a farm animal a plasmid vector encoding SEQ ID NO:1 (HV-GHRH, an optimized protease resistant

form of GHRH) under the control of a synthetic muscle specific promoter (SPc5-12). The site of injection was subsequently subjected to electroporation. See column 6, lines 15-24, column 22, lines 10-30. The method is intended to improve growth performance and increase the efficiency of the animal. See abstract, column 8, lines 24-60, and column 17, lines 31-34.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the promoter of '996 in the method of '693. One would have been motivated to do so because '996 taught that the SPc5-12 promoter greatly exceeds the transcriptional potencies of natural muscle specific promoters. See column 3, lines 45-50.

Although the cited references are silent with respect to an involuntary cull and body condition score, the combined references render obvious all of the claimed active method steps, so the functional effects of the methods are considered to be inherent.

Claims 15-17, 34-36, 52-54, 64, 70 and 76 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-23 of U.S. Patent No. 6,423,693, and Schwartz et al (US Patent 6,551,996), as applied to claims 1-9, 18-20, 22-28, 37-47, 55-61, 65-67, 71-73 above, and further in view of Fewell et al (US 2003/0109478).

The teachings of the '693 and '96 patents are discussed above. These references did not teach a transfection facilitating polypeptide.

Fewell taught a method of improving delivery of a nucleic acid expression construct to muscle cells in vivo comprising introducing into the muscle a nucleic acid expression construct and poly-L-glutamate, and electroporating the muscle tissue using needle electrodes. See entire document, e.g. first sentence of paragraph 109 at page 11, paragraphs 113 and 114, paragraph 123 bridging pages 12 and 13, paragraph 128 at page 13, and claim 79.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the poly-L-glutamate of Fewell in the method of '693 in order to obtain the reasonably expected improvement in delivery and expression.

Although the cited references are silent with respect to an involuntary cull and body condition score, the combined references render obvious all of the claimed active method steps, so the functional effects of the methods are considered to be inherent.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The official central fax

number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Richard Schnizer, Ph.D.
Primary Examiner
Art Unit 1635

Attachment 4

NCBI **Blast 2 Sequences**

PubMed Entrez BLAST OMIM Taxonomy Structure

BLAST 2 SEQUENCES

WARNING: First sequence must be nucleotide for this program

WARNING: Second sequence must be nucleotide for this program

Program [blastn] Matrix [Not Applicable]

Parameters used in BLASTN program only:

Match: [1] **Mismatch:** [-2]

Open gap [5] and extension gap [2] penalties

gap x_dropoff [50] expect [10.000] word size [11] Filter [☑] [Align] [Clear Input]

Sequence 1

Enter accession, GI or sequence in FASTA format from: [0] to: [0]

```
>seq_1
mpstgticsl lllsvllmad lamagssfls pehqkvqqrk eskkpaaklk
pralegwlgp edsgevegte dkleirfnap cdvgiklsga qsdqhgqplg
kflqdilwee vteapadk
```

Porcine Ghrelin

or upload FASTA file [ ] [Browse...]

Sequence 2

Enter accession, GI or sequence in FASTA format from: [0] to: [0]

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>seq_2
HVDAIFTNSYRKVLAQ
LSARKLLQDILNRQQG
ERNQEQGA
```

SEQ ID NO: 1

or upload FASTA file [ ] [Browse...]

[Align] [Clear Input]

Comments and suggestions to blast-help@ncbi.nlm.nih.gov